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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,494	08/17/2001	Trang T. Le	C-3320/1/US	5208

26648 7590 10/17/2006

PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,494	LE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,10-13,18-25,28-41,46-48,50-53,62-83,86-89 and 95-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/11/06 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 10-13, 21, 22, 28-41, 46-48, 50-53, 62-83, 86-89 and 96-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Love US 6,573,290 or Straub et al. US 6,395,300.

Mizumoto teaches a quick-dissolved compressed tablet comprising saccharide having high moldability and saccharide having low moldability (columns 6-7), drug, and additive agents (columns 13-19, claims 1-6). The blending ratio of high moldability and low moldability saccharides is from 2 to 20% by weight (column 7, lines 3-18). Drug is used in an amount of about 50% (column 10, lines 25-26). Drug includes both analgesic and anti-inflammatory agents (column 7, lines 13-15 and 39-41). The method

for preparing the tablet is disclosed in columns 12-13 (see also examples). The composition further comprises lubricant, *e.g.*, magnesium stearate, sucrose fatty acid ester, polyethylene glycol, or talc (column 13, lines 52-55). The hardness, strength, and disintegration time is disclosed at column 11, lines 30-60.

Mizumoto does not expressly teach the claimed surfactant, as well as the claimed active agent such as celecoxib. However, celecoxib is a well-known non-steroidal anti-inflammatory. To be more specific, Love teaches celecoxib is effective as a non-steroidal anti-inflammatory drug (nsaid) (abstract; and column 7, lines 60 through column 8, lines 1-38). Love also teaches the use of surfactant such as hydroxypropyl cellulose (column 11, lines 30-31; and column 12, lines 1-8).

Straub teaches nsaid includes celecoxib (column 4, lines 55-58). Straub further teaches processing celecoxib with excipient such as wetting agent or surfactant into tablet suitable for oral administration (column 3, lines 5-6; and column 8, lines 10-14). Wetting agent or surfactant includes fatty acid ester, polyoxyethylene alkyl ether, sodium lauryl sulfate, silicon dioxide, and combination of two or more (column 9, lines 3-67).

Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto for nsaid including celecoxib in view of the teaching of Love or Straub to obtain the claimed invention, because Love teaches celecoxib is a well known nsaid, because love teaches using celecoxib as an nsaid shows far less of the typical effect than other snaids (column 9, lines 1-7), because Straub teaches nsaid such as ibuprofen, ketoprofen, flurbiprofen, and celecoxib, because Mizumoto teaches the use

of stearic acid, polyethylene glycol *and the like* (column 13, lines 52-53), and because Mizumoto teaches non-steroidal anti-inflammatory such as ibuprofen, ketoprofen, flurbiprofen *and the like* (column 8, lines 13-15).

Claims 1-3, 10-13, 18-25, 28-41, 46-48, 50-53, 62-83, 86-89 and 95-100 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto et al. US 5,576,014, in view of Love or Straub et al., and Jain et al. US 6,316,029.

Mizumoto is relied upon for the reason stated above. Mizumoto does not explicitly teach the claimed surfactant.

Jain teaches a process for preparing rapidly disintegrating solid oral dosage form, wherein the rapidly disintegrating dosage form comprises surfactant including sodium lauryl sulfate, and one or more pharmaceutical excipients such as silicon dioxide (column 7, lines 15-67; and column 8, lines 59-64). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Mizumoto using the surfactant in view of the teaching of Jain to prepare a quick-dissolved formulation, because Jain teaches the use of surfactant as excipient in a quick disintegrating tablet is well known pharmaceutical art (column 7, lines 2-33; and column 8, lines 14-18), and because Mizumoto teaches the use of excipients in the composition. The expected result would be a compressed tablet having good hardness, and dissolved quickly upon contact with fluid.

The examiner notes that the cited references are silent as to the claimed amounts of glidant, and surfactant in claims 18-20 and 23-25. However, it is the

position of the examiner that no criticality is seen in the particular amounts since the prior art in using the claimed ingredients, obtains the same results desired by the applicant, *e.g.*, tablet comprising analgesic agent having disintegration rate of 1-40 seconds. See also *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant's arguments filed 08/11/06 have been fully considered but they are not persuasive.

Applicant argues that Straub teaches celecoxib among 410 drugs, and therefore, it would not led one of ordinary skill in the art to select celecoxib, and to prepare a composition as taught by Mizumoto. However, celecoxib is a well-known anti-inflammatory drug, and Straub is one of the prior arts that confirmed this fact. Love is cited for the specific teaching that celecoxib is the preferred nsaid (column 9, lines 1-7). Accordingly, one of ordinary skill in the art would have been motivated to select celecoxib to prepare a composition as taught by Mizumoto, because Mizumoto teaches a process suitable to prepare an nsaid formulation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Patent Examiner
Art Unit 1615